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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,659	01/23/2001	Kurt Nilsson	32067WC504391	2858

7590

08/26/2003

SMITH GAMBRELL & RUSSELL, L.L.P.  
Suite 800  
1850 M Street, N.W.  
Washington, DC 20036

EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/766,659

Applicant(s)

NILSSON ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 17-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892).
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 20, 21, 23, 27, 38, 43, 56, 66 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 20, line 2, “a smaller fragment” is vague and indefinite. It is unclear how “smaller” the fragment is. Similarly, claim 21 shares the same problem as claim 20.

With respect to 23, line 3, “OetSPhNH<sub>2</sub>” is vague and indefinite. It is unclear where the NH<sub>2</sub> is located with respect to the phenyl group.

With respect to claim 27, line 2, “via a chemical structure which has been adsorbed” is vague and indefinite. It is unclear what “adsorbed” applicant refers to, and where the structure adsorbed to.

With respect to claim 38, line 4, “with an organic group or an inorganic group” is vague and indefinite. It is unclear what “organic” and “inorganic” applicant refers to.

With respect to claim 43, line 2, “wherein the structure” lacks antecedent basis.

With respect to claim 56, line 3, “modified” is vague and indefinite. It is unclear what “modified” applicant refers to.

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With respect to claim 66, it is unclear how one skilled in the art to measure the presence or amount of the biomolecule. Applicant needs to specify the steps of how to measure the biomolecule.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 17-22, 24, 27-48, 55-58, 64-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson (USP 5372937) in view of Attridge et al. (WO 90/01166).

Nilsson teaches that carbohydrate structures are important for the stability, activity and immunogenicity, i.e. blood typing, in a variety of biological functions, e.g. receptor binding in recognizing pathogens, proteins, hormones, and toxin. (See Background, Col. 1, line 19-40) Nilsson teaches that oligosaccharides can be modified into glycoproteins or glycolipids for research purposes. (See Table 1 and 2) Nilsson also teaches using aglycon comprising a modified glycosidically bound, e.g. O-, N-, C- or S-aliphatic or

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aromatic compound where the aglycon can be conjugated with carboxyl group. (Col. 3, line 22-26, 30-33; claim 5) The aglycon can be served as a spacer. (Col. 4, line 3-8) The carbohydrate derivatives contain at least one of the monosaccharides include, galactose, A-acetyl-D-galactosamine, fucose. (claim 5) The aglycon molecules include 6-aminohexyl group which fits the formula of R-X, where R is the alkyl chain and X is the amino group. (Col. 4, line 7-11) However, Nilsson does not specifically teach immobilized the carbohydrate to a surface coated with gold, and apply optical detection to measure ligands in a sample.

Attridge et al teach that specific carbohydrate may be used as the biosensor receptor to bind lectins specific for the carbohydrate. Attridge et al. disclose a biosensor comprising a gold surface-immobilized carbohydrate for detecting a protein, virus, or cell by optical changes due to binding event, as discussed above. (page 5, line 3-7; Table 1, page 15, line 1-15, line 35-37; claim 1) The gold surface can also be coated with silica. (Claim 10) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Nilsson with the gold-surface immobilized carbohydrate derivatives as taught by Attridge et al. since it is known that the certain carbohydrate specific structures can be used to identify protein, virus, or bacteria and immobilized antigen-specific receptor, i.e. carbohydrate derivative, for detecting ligand is of great need for diagnosis purposes.

With respect to claims 55, 67-69, it has been held that a mere change in shape or form of a component is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955); *In re Japikse*, 86 USPQ 70. It would have been obvious to one skilled in the art to facilitate the modified carbohydrates taught by Nilsson in a particular shape or size since such changes only involves ordinary skill in the art.

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6. Claims 25-26, 49-50, 53 are rejected under 35 U.S.C. 103 (a) as being unpatentable Nilsson (USP 5372937) in view of Attridge et al. (WO 90/01166), as applied to the claims 17-22, 24, 27-48, 55-58, 64-69 above, and further in view of Hill et al. (USP 5496452)

Both Nilsson and Attridge et al. references have been discussed supra but are silent in using a protein as a binding vehicle, e.g. protein, for the carbohydrate to bind to the surface. Hill et al. teach using a protein, i.e. bovine serum albumin, as a vehicle to link the carbohydrate to avoid direct contact of the amino acid to the solid surface. (Col. 3, line 5-15) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided both the methods of Nilsson and Attridge with the bovine serum albumin as taught by Hill et al. as a linker to avoid the problem of attaching carbohydrates to the surface.

*Allowable Subject Matter*

7. Claims 23, 51-52, 54, 59-63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and overcome 35 U.S.C. §112, second paragraph rejections.
8. The following is an examiner's statement of reasons for allowance: no prior art teach or suggests that using aglycon selected from the group of OetSPhNH<sub>2</sub> and OEtSEtCONHNH<sub>2</sub>, or conjugating the biosensor in the formula as -R-NH-CO-CH<sub>2</sub>-CH<sub>2</sub>-S-biosensor, -R-X-Protein-NH-CO-CH<sub>2</sub>-CH<sub>2</sub>-S-biosensor where the protein comprises of bovine serum albumin. Moreover, no prior art teach modifying gold layer with mercaptopropionic acid, and using carbodiimide to modify the carboxyl group of the carbohydrate, whereafter Gal $\alpha$ 1-4Gal $\beta$ - OEtSEtCONHNH<sub>2</sub> is coupled to the surface. Similarly, no method teaches or suggests using the above modified carbohydrates to detect Gal $\alpha$ 1-4Gal specific receptor.

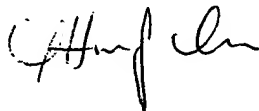
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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu



Examiner

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LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

08/22/03